The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics Meeting

January 6 -7, 2003

Introduction

The Centers for Medicare and Medicaid Services (CMS) convened its third Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain-Custom Fabricated Orthotics meeting at the Pikesville Hilton in Pikesville, Maryland on January 6-7, 2003. Commissioners Lynn Sylvester and Ira Lobel with the Federal Mediation and Conciliation Services (FMCS) facilitated the meeting. As indicated on the sign up sheet (attachment 3-1), all Committee members were represented. In addition to the Primary representatives, there were a number of Committee alternates, as well as a public audience in attendance.

The meeting agenda is in attachment 3-2. Ms. Sylvester announced that she received an email from the hand therapists withdrawing their request to make a presentation. After some discussion of the agenda, some agenda items were reorganized. It was decided that the two workgroups would report first with discussion and consensus votes being made after both presentations.

Approval of Minutes

Following this discussion, the minutes from the October meeting were reviewed and approved. It was agreed that in places where more accurate information had been requested, such information would be added to the minutes with reference to the fact that the information was provided at the subsequent meeting. It was also agreed that questions missed by the note taker would have to be submitted for possible inclusion by close of business on January 7 and that the minutes would also reflect that they were added later.

A question was raised about the inclusion of letters from the Hand Center and Donald Shurr as a part of the minutes. The facilitators suggested that the letters could be considered in any way deemed appropriate by committee members. After some discussion, it was agreed that these documents should be attached to the minutes as "public comment" and noted as such in the minutes. Any responses to these "public comments" would be based on preferences of individual committee members.

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Status Report form Data/Information Sub-Committee

John Michael again asked members of the committee to please fill out the affiliation spread sheet that he would be distributing during the sessions.

NOMA Presentation

The National Orthotic Manufacturers Association (NOMA) provided an overview of their association and membership. A copy of their presentation is in attachment 3-3.

Q: How many members does NOMA have and how is it structured?
A: Must remember that with trade associations it is not about the numbers but market share. NOMA represents about 75-80% of industry. There are about 12 members. Board is voted into positions and rotated. Members of the Board are all NOMA members.

Q. Who is the qualified provider?
A: We are Simply following the law, we will get into that discussion later.

Q. What are some of the acronyms?
A. ISO is the International Standards Organizations; it is set up to create international standards to recognize a process that creates consistent and appropriate products. It started in Europe and was adopted by the U.S. and much of the world. GMP (which means good manufacturing practices) and CE Mark (used in Europe) are similar to ISO and reflect good manufacturing practices, used mainly in the USA. ISO and GMP guidelines are beginning to mesh and are often very similar. If you meet one standard you meet them all. There are audits performed, Aircast is a relatively small company and has five people for ISO and is audited every other year.

Q. Regarding techniques of fabrication, with the CAD-CAM will "molded to patient" become obsolete?
A. My guess is that it would not be obsolete in its entirety, but will CAD CAM be used more and more. As manufacturers, we make devices to hit the majority of people. There will always be people who will need some additional care, so the process will not cover 100%. We are trying to make technology more and more sophisticated and make it easier to use. We put money into technology that a technician can use, with less education than a medical professional.

Q. With CAD technique is that what you use in your manufacturing process?
A. Yes. There are two forms of CAD CAM technology trace type and this type

Q. Do ISO 9000 techniques increase quality of patient care? Is this different that good manufacturing techniques?
A. Yes, but under ISO you must define customer requirements. Internally, we set a very high bar for what the customer wants. We do it to reach a quality process which helps you to make a quality product. ISO doesn't set the bar for you, but once you set the bar ISO requires that you meet it.

Q. What are educational levels or training for the sales force?

A. It depends on the individual company. NOMA does not set standards for education

Q. There is a concern that we will have to define the level of education for the sales force
A. If we follow the statute, I don't think there will be any problems with meeting the standards once we define them.

Q. What is the difference between supplier and manufacturer?
A. Not pertinent at this time.

Q. Does NOMA only address orthotic care
A. Yes.

Q. Do any NOMA representatives provide direct patient care?
A. They can. Aircast does not, I cannot answer for the other manufacturers.

Q. What is the source for the 75% of industry estimate?
A. It comes out of some reports like Frost and Sullivan, some propriety documents and some input from various sources

Q. Who are NOMA members?
A. We do not feel inclined to give names of actual members. Many NOMA members are here today you can go and introduce yourselves to them if you like.

Q. How old is NOMA
A. Formed about 10 years ago; all are believed to be members of AOPA.

Q. Is NOMA incorporated?
A. Yes, in DC within the last 2-3 years.

Budget for Future Meetings

The Officials from CMS representative stated announced to the committee that CMS is operating under a continuing resolution. They believed that they would have enough funding to keep the committee going until May, but could make no assurances after that. Funding is committed for the next four meetings, if the Committee requires them to complete its work. Two additional meetings can be scheduled, but additional budgetary allocations will be necessary if the Committee needs to meet thereafter.

Workgroup #1 Report

This workgroup, which focused on the inclusion of list items, presented a summary of their activities, thus far. Specifically, the group developed a decision tree of questions for determining which orthoses would be included within the statute. Workgroup #1's presentation is provided in attachment 3-4 and the actual decision tree is attachment 3-5.

There was discussion on many aspects of the decision tree, Terry Supan agreed to incorporate the changes for the next meeting.

Workgroup #2 Report

Conversely, workgroup #2 focused on developing a mechanism for determining what items would be excluded from the statute. This effort also included identifying those list of items that would clearly fall outside the statute. Using a word diagram (attachment 3-7), the workgroup was able to reach a consensus (and generically define) a number of terms. However, they were unable to reach a consensus regarding how to apply the term "over a positive model of the patient."

ISO 9000 Standards

Dr. Don Fedder noted that since the Board for Orthotist/Prosthetist Certification (BOC) has good relations with the ISO and American National Standards Institute (ANSI), he would offer to obtain written information regarding these standards for the next meeting. Committee members were interested in receiving this paper, but did not feel the need for a formal oral presentation.

Definitions for a Positive Model

On behalf of a separate ad hoc caucus, John Michael presented an overview of their approach to defining a positive model and the examples that would be included under this scope of understanding. Specifically, the workgroup identified three areas of stratification: (1) form (molded to patient model or molded to patient); (2) methods (3D or 2D); and (3) types of models (physical or virtual). They also identified nine potential case scenarios that could result in a "custom fabricated orthosis for one individual patient" (attachment 3-7). Mr. Michael reminded committee members that the workgroup was aiming at identifying the spectrum of scenarios and had made no judgments regarding which of these case scenarios would be inclusions/exclusions on the list.

Positive Model: Discussion on the General Approach

Following Mr. Michael's presentation, committee members had the following general questions/comments/concerns:

- **The definition of customized fit** -- While Mr. Michael acknowledged that the workgroup only included case scenarios where the end result was a customized fit; they did not have a formal working definition of the term, as a consensus on this definition had not yet been reached among committee members.

- **Terminology** -- Some terms were modified during the discussion. For example, it was tentatively agreed that "individually fabricated" should replace "custom fabricated over an individual patient." In addition, at least one committee member felt that the terms "actual" and "physical" were being used interchangeably. The opinion was that "physical" was the process while "actual" should refer to the model.

- **Process versus Outcome** -- Several committee members were concerned that this approach to develop a definition focused too much on the process and that the group might instead want to consider looking at the physical positive model as the end product. Other members indicated that the outcome should be the "custom fabricated device" which fits for one patient, with the term "positive" being the process.

Since a consensus could not be reached regarding the positive model definition it was suggested that there be a more detailed look at each of the case scenarios.

Positive Model: Discussion on the Nine Specific Case Scenarios

Following is feedback from the committee regarding the nine case scenarios for a positive model:

- **Case Scenario # 1 (MTPM 3d Physical)** -- A consensus was reached that this case would be included under the statute.

- **Case Scenario # 2-4 (MTPM 3d Virtual)** -- A number of committee members found the virtual model (e.g., CAD and CAM) problematic. Concerns about the use of "virtual" included:
    - It is not directly mentioned in the statute.
    - It would create a large loophole for getting an exclusion from the statute.
    - It might impede an important and growing industry, that has proven to be cost-effective.
    - It is the "wave of the future" and would have an even increasing relevance and role in the making of orthotic devices.
    - It still requires some level of clinical skill and a good degree of sophistication.
    - In many instances, its use is merely as a tool or process, so the committee may need to distinguish between design (CAD) and manufacturing (CAM) in its inclusion/exclusion discussions.

Some committee members also requested more information regarding CAD/CAM. For example, what is its prevalence and level of quality? While some members provided positive feedback on its use, others noted that the research on its usage is still inconclusive.

Positive Model: NOMA's Proposal for Addressing Definition

When the committee was unable to resolve their concerns about the "virtual model," NOMA (along with other organizations who had concerns), offered to develop a compromising proposal to get past the process language. Specifically, NOMA offered to develop a document that could be presented to their individual Boards (along with any other committee Member Boards that have concerns) in an attempt to broker an acceptable compromise that "everyone could live with." NOMA committee member, Stuart Kurlander, noted that the proposal would also attempt to define acceptable wording for "positive model" and a strawman list of excluded L Codes. The aim of the document would be to provide acceptance and consensus on Case scenarios 2-7.

As a caveat to this proposal, members who participated in a caucus surrounding the issue, noted that the committee should expect NOMA's proposal to classify orthosis provided at a physician's office under direction of a physician as an exclusion to the statute (i.e., NOMA constituents would be able to do castings/fittings that would be directed by a physician). Again, some committee members had issues with this, but were reminded that compromises were going to be necessary and that other concessions by NOMA may offset these concerns.

The facilitators also assured committee members that all members would ultimately have an opportunity to discuss and review the proposal and that no final decisions would be made without the group's consensus. While some committee members still expressed concern about this approach (e.g., difficulties with getting their boards convened, problems with developing the definition in the absence of defining a qualified provider, etc.) there was a consensus that committee members would table their objections until the written proposal was disseminated.

Decision Tree

The committee members then revisited the decision tree (attachment 3-5) developed by workgroup #1 to determine where there were areas of consensus. Some of the concerns that were identified included:

- **Order of the decision tree items** -- Committee members felt that some of the items should be reordered as a point of convenience (the bulk of exclusions would be made more quickly). Specifically, it was suggested that question 5A be moved up on the chart as this would cull down the eligible HCPC lists considerably. While many committee members agreed, the facilitator suggested that any discussion on the ordering of items be tabled until some consensus regarding the contents of the decision boxes was reached. This was particularly important as 5A had proven to be a stumbling block for both groups, and to go directly to that item might again stall discussions.

- **Issue of modifiers** -- Some committee members were concerned that modifiers might differ from their base codes. One committee member noted that the fundamental view has traditionally been to assess by claim (which reflects the base code).

- **Relevancy of each of the decisions --** There was some discussion on whether all five questions were needed. It was pointed out that while some of the questions (e.g., 3A) may only exclude a few HCPCs, they still had relevancy in culling down the universe.

Following is the discussion and results based on each item (see attachment 3-5 for reference):

- **Box 1 A** -- A consensus was reached regarding the inclusion of and wording used.

- **Box 1 B** -- It was clarified that the intent of this box was to address those approximately 60 stand-alone codes. CMS representative, Dr. Hugh Hill, requested a caucus to clarify the implications, and following the discussion, noted that the agency could support the implications. A consensus was then reached regarding the inclusion of 1B and the wording used.

- **Box 2 A --** The discussions regarding 2A revolved around two key issues/terms (1) fitting and (2) and prescription:

  (1) Custom fitted -- Two committee members noted that for the parenthetical box which states "custom fabricated and fitted," the term "fitted" is not in the statute and should be stricken from the record. Others members noted that generation of the term was within the Committee's authority for "deemed" status discussed in an earlier meeting and that the term was essential for distinguishing between custom "made" and "fitted".

  It was noted that there had been past problems with items being mailed without being professionally fitted and this would address that. It was suggested that the term "furnished" be used rather than "fitted." Consumer representatives expressed concern regarding implications for double billing (for making and fitting). It was also mentioned that the "fitting issue" would be addressed under the qualified provider section of the statute.

  (2) Prescription -- Since prescription was not in statute and the qualified practitioner discussion would obviate this mention, it was suggested that the term be removed. However, several committee members felt that the prescription section was needed for culling down the list because it would address replacements, repairs and modification adjustments. At least one committee member was concerned about the mold and measurement terminology, so the

section was revised to read, "Is the orthosis individually fabricated for a specific patient from a prescription.
While the Committee was unable to reach a consensus regarding 2-A, there was a consensus to leave the prescription component in this section.

- **Box 3A --** This item was reordered with 3A (i.e., switched), but the content was not discussed.

- **Box 4 A --** In general the Committee was okay with this section, though some thought it was redundant. However, no consensus vote was taken.

- **Box 5** -- Since question 5 led to the positive model definition the group decided that this section should wait until there were some decisions regarding the positive model.

Key Definitions

At one point on Day Two, the group reviewed the following three definitions, which they felt were critical (particularly for the development of NOMA's proposal discussed on page 4). These included (1) made to measure; (2) positive model of patient and (3) certain custom. A discussion of each is provided below:

- **Made to Measure** -- While this term is not specified in the statute, it was explained that the term was needed in order to accommodate instances where the orthotic devise was made by selecting and modifying an existing template (which was in general thought to be excluded from the statute). Together, the committee drafted the following terminology:

  Definition: Made to measure techniques of custom fabrication involves:

  1) taking multiple measurements of the patient
  2) selection and adjustments of pre-existing template
  3) fabrication of orthosis over selected templates and
  4) no postproduction rectification.

  At least one committee member stated that for a complex case and device, there may be some made to measure devises that should be included in the statute. In other words, the definition means that the inclusion/exclusion would be decided during the rectification process. For example, spinal products almost always entailed quite a bit of post-production rectification. This was acknowledged and it was pointed out that the rectification question on the decision tree would clarify the inclusion/exclusion of these exceptions.

  However, this approach raised a very difficult problem for groups like NASLTC which bill for these products but do not have control over the rectification after the product is made. According to one committee member, suppliers cannot be in

the business of making products with the "possibility" of being paid. They need to know at the time of order not after point of delivery. To address this concern, one participant suggested moving to product lists rather than the service-oriented L Code listings. Another suggested inserting the word "expected" next to post rectification. The facilitators suggested that while some progress had been made on this definition, this issue requires more discussion and should be resurfaced in later meetings.

- **Positive Model of the Patient --** Together, the committee drafted two potential versions for this terminology:

  Definition: Positive Model of the Patient is the appropriate replication of the anatomical structure of the patient that is to be encompassed by the orthosis but does not include custom made to measure orthosis.

  This eliminates the need to distinguish the type of medium that is used. Any medium that replicates that patient in anatomical structure would be covered.

OR

An anatomical replication of a body segment or structure of the patient necessary for the development for a custom-fabricated orthosis. This does not include an item molded directly over the patient.

While committee members were okay with this, they agreed that no consensus could be made until the definitions were combined.

- **Combined Definitions** - Using both definitions, the following terminology was proposed for the Positive Model of the Patient:

  An anatomical replication of a body segment or structure of the patient necessary for the development for a custom-fabricated orthosis, except as defined in number 1.

  This does not include an item molded directly over the patient.

  1. Made to measure techniques of custom fabrication involves:

  1) taking multiple measurements of the patient
  2) selection and adjustments of pre-existing template
  3) fabrication of orthosis over selected templates and
  4) no postproduction rectification.

While committee members felt that the right approach was being taken, there were several questions which included:

Amount of anatomy encompassed -- Did the anatomical replication just include the actual limb or other body parts that are affected by the device?

Made to Measure term -- Physician representatives asked for clarification regarding how products were made to measure. As the process varied and was also proprietary, this question was not fully addressed. Some committee members suggested using "clinical" as a more appropriate term, but no consensus was reached in this regard.

Patient as a Model -- As the statute says physical not patient model, representatives from the Occupational and Physical Therapists (OTs and PTs) wanted to be sure that patients as a model were excluded. In a practical sense, they were concerned that their members would be burdened with additional regulations or have limitations placed on their services with regard to work they did directly on the patient. The committee agreed that OTs and PTs were certainly qualified for these services, but thought that the qualified personnel discussion might address this. The OT/PT representatives noted that throughout Medicare regulations and at the State-level, OT/PT qualifications are synonymous with licensure and they were hopeful that the requirements from the Federal statute would not deviate from this common practice. A representative from AAPMR stated he considered the patient to be the perfect model.

Qualified Personnel

Questions regarding the "who" in addition to the "what" (i.e., the device) regulated by the statute resurfaced. The facilitators reminded the committee that while these were certainly interrelated and that it was very hard to work on issues related to inclusions/exclusions of devices until a qualified personnel definition was reached, it was suggested that these items not be commingled, just yet, because it would complicate an already difficult process. However, it was agreed that this should be a topic of discussion at the March meeting.

Due to scheduling problems, it was agreed that APTA and AOTA would develop a paper for distribution prior to the meeting. About five minutes on Day One, would be allotted to provide an overview and introduction on the qualified personnel topic.

Statute Clarification

There was some confusion on whether a device being excluded from the statute meant that no Medicare payment would be made. At face value, the statute seemed to indicate that this was the case. However, Dr Hill stated that he would pursue this internally within CMS, as he believed that this could be easily rectifiable (if that, in fact, was the case).

L Codes

During the conversations, there were several instances in which committee members recommended that the group begin reviewing L codes. The facilitators requested that this be an activity for the next meeting. Mr. Michael agreed to provide these codes (based on 2002 publishings) in advance of the meeting.

It was also suggested that Joel Kaiser from CMS be invited to the next meeting to provide a brief introduction regarding L Codes, as not all committee members may be fluent in the coding structure and terminology. Committee members also had questions about the potential for double billing (e.g., services and products). However, APTA noted that this was a very complex issue and was also outside of the scope of the statute and the committee's mission.

Prosthetics

There were a few requests throughout the meeting for having a consensus vote on the applicability of prosthetics. However, no vote was taken during this meeting.

Administrative Concerns

The following administrative concerns were also noted:

- **Ground Rule Reminders** --- The facilitators reminded committee members that they need to make a request to have their alternates provide comments during the formal sessions. They also clarified the use of caucuses and informed members that while these sessions are "off-the-record" to facilitate dialogue, the committee can be assured that all committee decisions would eventually need to be discussed and approved through the consensus process.

- **The Workings of Negotiations** -- During the more difficult discussions, the facilitators reminded participants that negotiations can be quite difficult. Strategies for overcoming these roadblocks include (1) putting aside some components of discussion until later (as was done with the qualified personnel discussions); (2) jumping around and being flexible (approaching something in several different ways in order to "chip away" at it); and (3) focusing on what everyone can "live with" and the issues behind their positions to see if there are creative alternative approaches for meeting everyone's needs.

- **Public Comments** -- The facilitators provided the opportunity for the audience to submit any public comments. None were noted. However, three written comments (3-10 a-c) are attached to these minutes.

- **May Meeting** -- Due to some scheduling conflicts, the May meeting has been rescheduled to May 19 and 20. Committee members were strongly encouraged to

make their lodging reservations early because the meeting was around the same time as the Maryland Preakness.

- **Disclosure Statements** -- Based on prior feedback, Mr. Michael developed a spreadsheet of declared disclosures made by each committee member representation. He asked the committee members to review and update the spreadsheet as needed, before the meeting adjourned.

- **Meeting times --** To accommodate participants' travel requirements, it was agreed that meeting times for day one would remain from 9:00 am - 5:00 pm, but on day two, meeting times would be modified to 8:00 am - 4:00 pm.

The AAOP representative requested at the February 10th meeting that the question from the January 7th meeting be placed in the minutes regarding the relationship between L codes and CPT codes when providing O&P services. The response was that this is a very complex question and answer.

The meeting adjourned on January 7th. The next meeting will be held at the Pikesville Hilton from February 10-11, 2003.

Action Items

1. Provide a paper to the committee regarding ISO 9000 standards (Dr. Don Fedder)

2. Provide a proposal for addressing the definitions of a positive model for presentation to committee member's individual boards. This may include their first attempt at categorizing inclusions/exclusions of L Codes (NOMA and PT, OT) within two weeks following this meeting.

3. Provide L Codes listings (J Michael based on 2002 publishings) by Wednesday, January 15, 2003.

4. Integrate the Decision tree with the definitions generated --Workgroup #1 by January 24, 2003

5. Get clarification regarding allowability for billing for those services outside the statute (Hugh Hill with CMS)

6. Develop paper on "Qualified Personnel (C Ellis and J Kass) prior to the next meeting.

7. Invite Joel Kaiser to provide overview of L Codes (Hugh Hill) -- tentatively done

8. Modify meeting date and travel plans for May to May 19-20 (all participants)

Topics for Next Agenda

- Qualified personnel overview (do on Day One for APTA scheduling concerns)
- Brief Presentation on CAD
- Review of L Codes (Joel Kaiser)
- Review of NOMA Proposal
- Consensus on positive model

Attachments from Meeting

3-1	Sign-up Sheet
3-2	Agenda
3-3	NOMA Powerpoint Presentation
3-4	Workgroup #1 Powerpoint Presentation on List of Items for Inclusion
3-5	Decision Tree (Workgroup #1)
3-6	Workgroup #2 PowerPoint Presentation on List of Items for Exclusion
3-7	Presentation on Definitions for Positive Model
3-8	Draft Definitions for "Made to Measure", "Positive Model of the Patient" and "Certain Customized"
3-9	Draft Spreadsheet on Committee Members Disclosure Statements
3-10(a)	Public Comment: Letter from Iowa
3-10(b)	Public Comment: Letter from Hand Therapist
3-10(c)	Public Comment: Letter from Michigan Hand Center